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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/454,252	12/02/99	PELLETIER J	248/037

EXAMINER

HM12/0815

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ART UNIT	PAPER NUMBER
1653	17

DATE MAILED: 08/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/454,252	PELLETIER ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 36-99* is/are pending in the application.

4a) Of the above claim(s) *38-60 and 65-92* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,36,37,61-64 and 93-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Election/Restriction

Applicants' election with traverse of Group I, claim 9 (in part), 36, 37, 61-64 and 93-99 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that all of claim Groups I-IV involve determination of protein binding, thus search of claims of Group I directed to protein bindings will include claims of Group II, III and IV, therefore, no additional burden would be imposed on the Examiner. This is not found persuasive because inventions I-IV are unrelated. Group I is drawn to protein binding or affinity assay and do not involve or require use of antibodies as in Group III; cross linking reagents as in Group IV; or DNA, as in Group II for its practice. Thus, each of Groups I, II, III, IV has a mode of operation that is distinct from the other. Furthermore, the search burden would be there as indicated by the different classification of each group. Applicants indicate that claims 54-58 of Group V should be considered as generic to all claim groups, as they address the target source, rather than the identification technique. However this is not found persuasive because group V is drawn to a method of identifying the coding sequence of a bacterial target, which is a different mode of operation and distinct from other groups. Claims 48-52 and 74-91 of Group VI drawn to a method of identifying a bacteriophage ORF encoding a bacterial inhibiting protein. Applicants argue that an inhibitory

phage ORF is identified to provide the encoded inhibitory ORF product, that is used for identifying the bacterial targets. Therefore, Group VI and Group V/VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the bacteriophage ORF of Group VI can be used for hybridization assay. Furthermore, the invention of Group VI has a mode of operation that is distinct from other Groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 38-60, 65-92 are withdrawn under 37 C.F.R. § 1.142(b) from further consideration by the Examiner, as being drawn to a non-elected invention.

Claims 9, 36-37, 61-64, 93-99 are pending and are under consideration in the instant application.

Objection to the Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 35, line 20; page 63, lines 13, 21-26, 28, 30 and 31). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 36, 37, 61-64, 93-99 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specifically disclosed method for identifying a target for antibacterial agent by determining the bacterial target of one bacteriphage inhibitor protein set forth in the specification, does not reasonably provide enablement for any method for identifying any bacterial target of any bacteriophage inhibitor protein, having any structure or any variation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 9, 93-95 are directed to a method identifying the bacterial target protein that binds to any uncharacterized bacteriophage inhibitor protein. No limitation exists in the claim to indicate the structure of the bacteriophage inhibitor protein. Specific sequences or structural motifs critical or essential to the practice of the invention, but not included in the claims are not enabled by the disclosure. The specification indicates a motif in bacteriophage 3A ORF corresponding to a Cecropin signature motif which was originally identified in known inhibitor proteins (page 64, Example 5), however, the inhibitory function of the sequence has not been demonstrated. Furthermore, the sequence alignment data of bacteriophage 77 ORF on page 124, Table 5, does not indicate any motif corresponding to the Cecropin motif of bacteriophage 3A ORF. It would require undue experimentation for a person having ordinary skill in the art to be able to practice the claimed invention because no guidance has been provided such that a person

having ordinary skill in the art would know the structure with reference to the binding site of the bacteriophage inhibitor protein. There is no description given for a binding assay wherein it demonstrates the binding of a bacteriophage inhibitor protein to a bacterial target protein. The nature of the invention relates to the generation of any sequence encoding bacteriophage inhibitor protein but no indication has been made as to what activity the encoded protein must have.

Claim 36 is directed to a method wherein the binding is determined using affinity chromatography on a solid matrix. Specification fails to provide a specific description for the condition of the assay for the binding of bacteriophage inhibitor protein to the bacterial target protein.

Claims 61-64 and 97-99 are directed to a method, wherein, the bacterial target protein binds to a fragment of bacteriophage inhibitor protein. No biological activities were attributed to the recited protein fragments and the structural information was limited (see page 4 of this office action). There is no disclosure about the binding activities of claimed fragments. Therefore, undue experimentation would be required to make and use the claimed protein fragments.

The specification describes on page 5, second paragraph that the term "uncharacterized" means that a certain bacteriophage's genome has not yet been fully identified such that the genes having function involved in inhibiting host cells have not been identified. If a genome is not fully identified then how one would know the identity of exons, introns and the regulatory sequences of that genome, how one would know an exon that encodes a protein having inhibitory function in the host cell.

As for "potential target" of claim 93 how one would assess a "potential" versus "real" target. Although specification on page 6 has defined a "target" as a biomolecule that can be acted on by an exogenous agent, however there is no indication of what a "potential target" is, neither there is any guidance to asses the nature of that target, for example whether it is a DNA or a protein or a membrane lipid or a cell wall structural component. Furthermore, what does one do with the identified "potential target"? The disclosure does not indicate a real world process of use of the "potential targets" neither it indicates a mechanism involved to identify antibacterial agents for these targets.

The specification has demonstrated the ORF of bacteriophage 77 and its expression in *Staphylococcus aureus* in Examples 1-6, pages 60-66, however the specification fails to describe or demonstrate the invention as claimed in claim 9, for example i) identifying a potential target for antibacterial agent, ii) determining a bacterial target of an uncharacterized bacteriophage inhibitor protein.

Therefore, in view of the degree of guidance given in the specification and the limited exemplification of the method using bacteriophage inhibitor protein, coupled with the unpredictability associated with sequence prediction based on activity, it would require undue experimentation for a person having ordinary skill in the art to be able to practice the claimed invention without further guidance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 9, 93 and dependent claims 36, 37, 61 and 94-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Use of the word "uncharacterized" in claim 9 with reference to the bacteriophage inhibitor protein is indefinite. Likewise, the word "untargeted" in claim 93 with reference to the bacteriophage inhibitor protein is indefinite. The meaning of "uncharacterized" and "untargeted" when referring to bacteriophage is ambiguous because it is not clear what would be that bacteriophage which has not been characterized and which has not been targeted and has not been targeted for what? How would one know where the uncharacterized bacteriophage inhibitor protein had been determined. The claim lacks steps to accomplish the method. Claims 61 and 96 are indefinite as to fragment size, which can be a single aminoacid so it is unclear what the minimum size of the fragment is supposed to be. Claim 93 is indefinite as to "potential target", either it is a target or it is not.

Claims 37 and 96 are rejected because they are dependent on a rejected base claim.

Conclusion

No claim is allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr.Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rita Mitra, Ph.D.
August 10, 2001

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